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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,529	05/10/2002	Achim Berthold	512100-2025	6199

20999 7590 03/15/2004

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,529	Applicant(s) BERTHOLD ET AL.
	Examiner Isis Ghali	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/3/2002.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 06/03/2002; and priority papers, filed 06/05/2002.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

5. The use of the trademarks "Span", "Celgard", "Solupor", "CoTran", "BIO-PSA Q7-4301", "Scotchpatch", "Surlyn" have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

6. Claims 5-12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2, 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, the word "palmitate" is misspelled as "palminate".

Regarding claim 8, the claim provides for the use of calcium antagonist, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35

U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Regarding claim 9, the claim is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. The expression "other cardiovascular diseases" does not set out the metes and bounds to the claim. Recourse to the specification, applicants do not disclose all "other cardiovascular diseases".

With regard to claim 10, the claim is directed to: "a solution which is suitable for use in a transdermal therapeutic system", while the claim reads as: "the solution comprising a drug reservoir containing solution comprising -----." Clarification is requested.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,983,395 ('395) in view of US 4,879,119 ('119).

US '395 discloses a transdermal drug delivery device comprising a drug formulation containing reservoir defined by a backing layer and a drug permeable membrane layer, and a peelable release liner (abstract; col.2, lines 30-57). The reservoir comprises ethanol, enhancer, and nicardipine (col.7, lines 55-60). The reference disclosed nifedipine as one of the dihydropyridines that are suitable to be included in the reservoir (col.5, line 25).

The reference does not teach the pyrrolidone derivatives, sorbitan palmitate as specific enhancers, or lacipidine species of dihydropyridines. The reference does not teach specific amounts of different ingredients as claimed.

It is within the skill in the art to replace one species by another known to perform the same function. Thus, claiming lacipidine does not render the claim patentable, absent evidence to the contrary.

The amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

US '119 teaches a skin patch having good transdermal properties showing increased skin penetration rate of the drug and an increased drug releasing rate (abstract; col.1, lines 9-12). The good transdermal properties are provided by a patch comprising a solution comprising the drug and penetration enhancer, such as sorbitan middle chain fatty acid ester (abstract; col.3, lines13-15). Drugs suitable for delivery by those patches are nicardipine and nifedipine dissolved in ethanol, N-methyl-2-pyrrolidone or mixture thereof (col.2, lines 33-34; col.49-58).

Thus, it would have been obvious to one having ordinary skill in the art a the time of the invention to provide a transdermal patch comprising reservoir comprising dihydropyridine, ethanol, and penetration enhancer as disclosed by US '395, and add the pyrrolidone derivative and the select sorbitan ester as an enhancer as disclosed by US '119, motivated by the teaching of US '119 that a patch with such ingredients has good transdermal properties showing increased skin penetration rate of the drug and an increased drug releasing rate, with reasonable expectation of having a transdermal drug delivery device to deliver dihydropyridine in a reservoir comprising ethanol, pyrrolidone derivative and sorbitan ester that deliver the drug to the patient in need with great success.

12. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,045,553 (553) in view of US '119.

US '553 teaches a pharmaceutical composition for percutaneous drug absorption comprising dihydropyridine compound to treat hypertension and angiopathy (abstract; col.1, lines 34-37). The composition is included in a patch comprising a support member, drug-containing layer, and release controlling membrane (col.2, lines 35-40; figures 1-6; col.4, line 12). The composition comprising nilvadipine in an amount of 5% by weight, unsaturated fatty acid, and pyrrolidone derivative (col.2, lines 45-61; col.4, lines 49-50; examples).

The reference does not teach the specific pyrrolidone derivatives, sorbitan palmitate as specific enhancers, or lacipidine and nifedipine species of dihydropyridines. The reference does not teach specific amounts of different ingredients as claimed.

It is within the skill in the art to replace one species by another known to perform the same function. Thus, claiming lacipidine or nifedipine does not render the claim patentable, absent evidence to the contrary.

The amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

US '119 teaches a skin patch having good transdermal properties showing increased skin penetration rate of the drug and an increased drug releasing rate (abstract; col.1, lines 9-12). The good transdermal properties are provided by a patch comprising a solution comprising the drug and penetration enhancer, such as sorbitan middle chain fatty acid ester (abstract; col.3, lines13-15). Drugs suitable for delivery by those patches are nicardipine and nifedipine dissolved in ethanol, N-methyl-2-pyrrolidone or mixture thereof (col.2, lines 33-34; col.49-58).

Thus, it would have been obvious to one having ordinary skill in the art a the time of the invention to provide a transdermal patch comprising reservoir comprising dihydropyridine, ethanol, and penetration enhancer as disclosed by US '553, and select sorbitan ester as an enhancer as disclosed by US '119, motivated by the teaching of US '119 that a patch with such ingredients has good transdermal properties showing increased skin penetration rate of the drug and an increased drug releasing rate, with reasonable expectation of having a transdermal drug delivery device to deliver dihydropyridine in a reservoir comprising ethanol, pyrrolidone derivative and sorbitan ester that deliver the drug to the patient in need with great success.

13. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 680 759 ('759) in view of US '119.

EP '759 teaches a transdermal delivery of calcium channel blockers, such as nifedipine to treat angina and hypertension (abstract; page 2, lines 50-53). The device comprises a backing layer, a reservoir containing the drug, and a semi-porous membrane (page 6, lines 15-28; page 8, lines 10-14). The reservoir comprises the drug, ethanol, and permeation enhancer (abstract; page 7, lines 39-55).

The reference does not teach the pyrrolidone derivatives, sorbitan palmitate as specific enhancers, or lacipidine species of dihydropyridines. The reference does not teach specific amounts of different ingredients as claimed.

It is within the skill in the art to replace one species by another known to perform the same function. Thus, claiming lacipidine does not render the claim patentable, absent evidence to the contrary.

The amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

US '119 teaches a skin patch having good transdermal properties showing increased skin penetration rate of the drug and an increased drug releasing rate (abstract; col.1, lines 9-12). The good transdermal properties are provided by a patch comprising a solution comprising the drug and penetration enhancer, such as sorbitan middle chain fatty acid ester (abstract; col.3, lines13-15). Drugs suitable for delivery by those patches are nicardipine and nifedipine dissolved in ethanol, N-methyl-2-pyrrolidone or mixture thereof (col.2, lines 33-34; col.49-58).

Thus, it would have been obvious to one having ordinary skill in the art a the time of the invention to provide a transdermal patch comprising reservoir comprising dihydropyridine, ethanol, and penetration enhancer as disclosed by EP '759, and add the pyrrolidone derivative and the select sorbitan ester as an enhancer as disclosed by US '119, motivated by the teaching of US '119 that a patch with such ingredients has good transdermal properties showing increased skin penetration rate of the drug and an increased drug releasing rate, with reasonable expectation of having a transdermal drug delivery device to deliver dihydropyridine in a reservoir comprising ethanol, pyrrolidone derivative and sorbitan ester that deliver the drug to the patient in need with great success.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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ISIS GHALI
PATENT EXAMINER